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Appl. No.: 09/842,466 Confirmation No.: 8005
Applicant(s): Kokubo et al.
Filed: 04/26/2001
Art Unit: 1616
Examiner: H. Sheikh
Title: SOLID PREPARATION COATED WITH A FILM COATING LAYER AND
FILM COATING AGENT

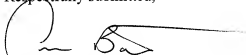
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**APPEAL BRIEF TRANSMITTAL
(PATENT APPLICATION - 37 C.F.R. § 41.37)**

1. Transmitted herewith is the APPEAL BRIEF in this application, with respect to the Notice of Appeal filed on July 2, 2008.
 2. ☐ Applicant claims small entity status.
 3. Pursuant to 37 C.F.R. § 41.20(b)(2), the fee for filing the Appeal Brief is:
☐ small entity \$255.00
☒ other than small entity \$510.00
Appeal Brief fee due: \$510.00
- ☒ Any additional fee or refund may be charged to Deposit Account 16-0605.

Respectfully submitted,



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APPEAL BRIEF UNDER 37 CFR § 41.37

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed July 2, 2008.

1. ***Real Party in Interest.***

The real party in interest in this appeal is Shin-Etsu Chemical Co., the assignee of the above-referenced patent application.

2. ***Related Appeals and Interferences.***

There are no related appeals and/or interferences involving this application or its subject matter.

3. ***Status of Claims.***

Claims 6 – 9, 11, 13 – 20, and 31 – 47 are pending and all claims stand finally rejected as unpatentable over a combination of references as set forth in greater detail below. The prior art rejection of Claims 6 – 9, 11, 13 – 20, and 31 – 47 is appealed herein.

Claims 1 – 5, 10, 12, and 21 – 30 have been cancelled.

4. ***Status of Amendments.***

No claims were filed subsequent to the Final Office Action.

5. ***Summary of Claimed Subject Matter.***

The present invention as embodied in independent Claims 31 and 33 is directed to a solid preparation having a continuous multicolored coating layer. The continuous multicolored coating is provided by coating a solid preparation with a continuous coating layer having one or more colorants. Portions of the coating layer are then selectively exposed to radiation, such as light, in an amount that is sufficient to cause a change in color in the colorants that are exposed to the radiation.

By way of background, it is increasingly desirable to distinguish different medicines from each other based on color, size, or shape. This is particularly true in view of the aging population and the number of patients who must take multiple medicines. For example, distinguishing medicines from one another is very important in order to prevent mistakenly administering or consuming the incorrect medicine.

Many medicines are available as solid preparations that can be ingested. Two common forms of such solid preparations include capsules and tablets. Generally, tablets comprise a powder medicine that has been compressed into a desired shape. Capsules on the other hand generally include a two piece outer shell in which the medicine is disposed. The pieces of the outer shell, also referred to as caps, comprise a dissolvable film. The caps comprising the outer shell are often a different color from each other so that the resulting capsule is multicolored. Multicolored solid preparations are desirable because they help facilitate easy identification and can also be used by manufactures in branding their particular product. Capsules have gained

popularity due to their ease on ingestion, lack of unpleasant taste that can often be associated with tablets, and the ability to be produced to have two or more colorings.

In the early 1980's it was learned that the two-piece outer shell of the capsules were susceptible to tampering. As a result, many pharmaceutical makers chose to provide solid preparations in the form of tablets to prevent tampering. To maintain many of the desirable properties of capsules, a film coating is applied to the tablets. However, the coatings of the film-coated tablets had only a single color and did not have the desirable multicolor shells that were available in capsules. To provide a multicolored coated tablet, various methods have been developed. For example, coated tablets have been produced in which two tableting powders having different colors are compressed together to make a multicolored tablet. However, the resulting coated tablets tend to be weakened and crack at the interface of the powders. Other methods include dipping a pre-coated tablet in two different film solutions having different colors. Typically, this process requires specialized equipments and complicated steps. As a result, the prior art has not provided a simple and efficient means of providing multicolored tablets/pills.

The invention defined in independent Claims 31 and 33 is directed to a solid preparation having a continuous multicolored coating layer. See page 9, lines 21 – 24 and FIG. 4, reference characters A and B. As discussed on page 9, lines 1 – 9, a solid preparation having a multicolored continuous coating layer overcomes many of the problems associated with prior art methods, such as low strength and inefficient or complex production process, as well as providing a solid preparation having two or more colors that helps facilitate distinguishability and identification of the solid preparation.

Independent Claim 31 recites a solid preparation having a multicolored continuous film coating layer. Claim 31 further recites that the solid preparation is formed by first coating a solid preparation with a coating layer having one or more colorants. See generally page 11 line 18 through page 13, line 25. In a subsequent step, a first part of the coating layer and a second part of the coating layer are irradiated with light in an amount that is sufficient to cause the first and second parts of the coating layer to have different colorations with respect to each other. For example, as discussed on page 19, lines 7 – 21, a first part of the solid preparation can be

irradiated with an amount of radiation that causes a color change in the first part, while the amount of radiation to which the second part of the solid preparation is exposed is insufficient to result in a color change. As a result, a solid preparation having a multicolored continuous film coating layer is provided.

Similarly, independent Claim 33 recites a solid preparation having a multicolored continuous coating layer that is created by changing the coloration of one or more parts of the coating layer by irradiating those parts of the coating layer to the exclusion of the remainder of the coating. As discussed on page 18, lines 1 – 17, the multicolored continuous coating can be provided by irradiating a first region of the coating with light while shielding a second region of the coating from the light.

The claimed invention also advantageously provides a solid preparation that can have a continuous coating in which a pattern in the form of a bar code, logo, letters, and the like are created directly in the coating of the film without the requirement of an additional printing or engraving step. For example, a photomask having a desired pattern can be used to selectively shield a portion of the continuous coating from being irradiated with light so that exposure to a sufficient amount of irradiation forms the desired pattern in the continuous coating layer. See generally page 23, lines 1 – 19.

6. *Grounds of Rejection to be Reviewed on Appeal.*

Claims 6 – 9, 11, 13 – 20, and 31 – 47 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,820,524 to Berta in view of U.S. Patent No. 6,406,738 to Hogan et al.

The Office Action alleges that Berta teaches a capsule-like medicant having a solid core that is coated with a multi-colored gelatin single coating layer, and therefore describes the claimed solid preparation. The Office Action further alleges that although the multi-colored tablet is prepared differently than the claimed tablet, it is the product that must be patentable and not the process by which it is made.

The Office Action also cites Hogan for allegedly teaching a method of applying radiation to a powder coating material to provide a medicant (i.e., tablet) having a multi-colored

continuous coating, and therefore it would be obvious to treat the multi-colored tablet of Berta with radiation as taught in Hogan to arrive at the claimed invention.

7. ***Argument.***

The Examiner has failed to make a *prima facie* case of obviousness because 1) the combination of references fails to teach each and every claim element and 2) because there is no motivation to combine the references. Specifically, the combination of references fails to teach a solid preparation having a continuous multicolored film coating layer. Further, the combination of the references fail to disclose or suggest the steps that are necessary to arrive at the claimed invention and therefore fail to disclose or suggest the claimed structure that is arrived at with the claimed method steps.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim elements. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). It is respectfully submitted that the Examiner has failed to meet any of these criteria and therefore the rejections should be reversed.

A. **The Combination of Berta and Hogan Does Not Disclose or Suggest Each and Every Element of Independent Claims 31 and 33.**

Applicants respectfully submit that the combination of Berta and Hogan fails to disclose or suggest the claimed invention. Specifically, the combination of the cited references fails to disclose or suggest a solid preparation having a multi-colored continuous film coating layer.

The combination of the references fails to disclose or suggest a solid preparation having a multi-colored continuous coating. Berta teaches a tablet having a multi-colored coating that is

obtained by individually dipping and drawing first one end and then the other end of each tablet into a bath of gelatinous coating. See Abstract. In particular, Berta describes that an exposed end is dipped into the bath and then dried. After drying, the uncoated end is dipped into a second bath and then dried to provide a multi-colored coating. See column 5, lines 48 – 65. From this excerpt, it can be seen that the coating described in Berta is not a single continuous coating, but rather comprises two separate coatings that are separately applied to each half of the tablet. Thus, Berta does not disclose or suggest a solid preparation having a multi-colored continuous film coating layer as recited in independent Claims 31 and 33.

Hogan also fails to disclose or suggest a solid preparation having a multi-colored continuous film coating layer. Hogan describes a process for preparing a multi-colored tablet in which a first coating powder is electrostatically applied to one portion of the tablet followed by exposing the coating to electromagnetic radiation, such as infrared radiation, to cause the powder to melt and form a liquid. See column 4, lines 32 – 44. Upon cooling, the liquid forms a coating on the surface of the tablet to which it has been applied. In a subsequent step, a second coating powder of a different colorant is electrostatically applied to the uncoated portions of the tablet, followed by exposure to electromagnetic radiation as described previously to form a multi-colored tablet. From this discussion, it can be seen that the multi-colored coating of Hogan also comprises two distinct coatings that are separately applied to the tablet. As such, Hogan teaches a tablet having two separate coatings covering distinct halves of the tablet and does not have the presently claimed multi-colored continuous coating layer.

In contrast to the cited references, independent Claims 31 and 33 recite a solid composition having a multicolored continuous film coating layer. As noted above, both Berta and Hogan describe tablets/caplets having two separate coatings that are separately applied to the solid preparation. Accordingly, Berta and Hogan do not disclose or suggest the claimed invention when considered singly or in combination.

Further, the combination of references fails to disclose or suggest the step of selectively irradiating the continuous coating to produce a coating having two distinct colors. This step is neither suggested nor disclosed by the cited references. In fact and as discussed in greater detail below, there is no teaching in either of the references that irradiating the coating would produce

any sort of color change in the coatings. As such, the combination of the references fails to disclose or suggest the steps that are necessary to arrive at the claimed invention and therefore fail to disclose or suggest the claimed structure that is arrived at with the claimed method steps. That is, the cited references fail to disclose or suggest a process that can be used to prepare a solid composition having a multicolored continuous film coating layer.

From the foregoing discussion, it is clear that the combination of Berta and Hogan fails to disclose each and every element recited in independent Claims 31 and 33. It is respectfully requested that the rejection of Claims 6 – 9, 11, 13 – 20, and 31 – 47 be reversed.

B. One of Ordinary Skill in the Art would not be motivated to combine Berta and Hogan as contemplated by the Examiner.

The Examiner asserts that it would be obvious to one of ordinary skill in the art to incorporate the powder coating material methods of Hogan, which comprise the step of applying radiation, within the multi-colored tablets of Berta. The Appellants disagree with this assertion for several reasons.

First, one of ordinary skill in the art would not be motivated to irradiate the tablet of Berta because to do so would serve absolutely no purpose. As discussed above, Berta describes a process of preparing a multi-colored tablet in which a multi-colored coating is obtained by individually dipping and drawing first one end and then the other end of each tablet into a bath of gelatinous coating. Each end is dipped into its respective bath and then dried. Berta describes that each bath includes a different colorant so that the resulting tablet has two coatings of different coloring. In contrast, the process of Hogan describes a process in which electrostatically charged particles are irradiated to melt the particles together to form a coating. The thus formed liquid coating is allowed to cool to form a solid coating on the portion of the tablet to which the particles have been electrostatically adhered. Accordingly, the irradiation step in Hogan is necessary in order to melt and fuse the particles together in order to form a coating. Such a step is unnecessary in the process of Berta and would in fact serve no purpose because the coating of Berta is provided as a liquid and as such there is no reason to apply irradiation to fuse the coating together as in Hogan. In fact, such a step would be counter

productive because it would prevent or hinder the drying of the gelatinous coating. It cannot be predicted what would happen if the coatings of Berta were exposed to the irradiation step of Hogan (see discussion in Section C below). It is probable that such a step would result in melting the coating of Berta. Accordingly, one of ordinary skill in the art would not modify the process of Berta to include the step of irradiating the coating as taught in Hogan.

Second, both Hogan and Berta teach using separate coating materials of different color to form a multi-colored coated tablet. For instance, Berta teaches dipping a first exposed portion of the tablet into a bath of a first color, followed by dipping a second exposed portion of the tablet into a second bath of a different color to obtain a multi-colored tablet in which the two portions of the tablet are of different colors. Having thus obtained the multi-colored tablet, one of ordinary skill in the art would not be motivated to then expose selective regions of the tablet to irradiation to obtain a further color change. Such a step would serve absolutely no purpose since the tablet of Berta has previously obtained the desired multi-colored appearance. As such, one of ordinary skill in the art would not be motivated to irradiate the tablets of Berta.

Finally, neither Berta nor Hogan include any teachings that their respective coatings would change color upon being irradiation. There is absolutely no basis for suggesting that the irradiation step of Hogan would result in changing the color of the coatings of either Berta or Hogan. In fact, the only possible suggestion for such a step comes from Applicants' own teachings. It is clear that the Examiner is using Applicants' own teachings in making this rejection. This is impermissible use of hindsight. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). For this additional reason, one of ordinary skill in the art would not be motivated to modify the process of Berta to include the step of irradiating the coatings as taught in Hogan.

The Examiner also asserts that Hogan teaches applying radiation, such as ultraviolet light, to the tablet. However, this teaching is directed to curing the coating to form a cross-linked polymer film. There is absolutely no teaching in Hogan of using radiation to selectively effect a color change in the tablet coating, or as noted above, that the coatings of Berta or Hogan would even be susceptible to changing color by being exposed to radiation, such as ultraviolet light. The Supreme Court in *KSR v. Teleflex* (*KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, USPQ 2d

1385 (2007) stated that the Examiner must provide an explicit explanation as to an “apparent reason to combine the known elements in the fashion claimed by the patent at issue.” Here, the Examiner has failed to provide any rationale explanation as to why of ordinary skill in the art would employ the irradiation step of Hogan in combination with the multi-colored tablet of Berta. Thus, the Examiner has failed to provide any motivation as to why one of ordinary skill in the art would modify Berta as contemplated by the Examiner. For this additional reason, the Appellant respectfully requests that the Board reverse the rejection of Claims 6 – 9, 11, 13 – 20, and 31 – 47.

C. The combination of Berta and Hogan does not provide predictable results.

In *KSR*, the Supreme Court held that in determining obviousness, one must look to whether the combination of the elements provides a predictable result. In the present case, one of ordinary skill in the art would not be motivated to use the irradiating step of Hogan in the process of Berta because the result would be unpredictable. Accordingly, there can be no expectation of success.

As noted above, there are absolutely no teachings in the cited references that the irradiation would effect a color change in any one of the coatings of Berta or Hogan. As such, the irradiation step of Hogan cannot be applied to the tablet of Berta in a predictable manner because there is no teaching on how such a step would affect the coatings of Berta.

Further, it cannot be predicted how irradiation would affect the structure of the coatings of Berta. As discussed above, the irradiation step of Hogan is provided to melt the individual particles of Hogan so that upon cooling they are able to fuse together to form a coating. In contrast to Hogan, the coatings of Berta are applied as a liquid gelatinous coating that is then dried. In other words, there is no need to melt the coating because it is already a liquid. As such, applying the irradiation step to the coating of Berta may cause the individual coatings on each half of the tablet to melt, which can result in portions of the melted coatings running together or dripping off the tablet. This would result in the tablet losing uniformity in the coating, which in turn, would result in the tablet having an unsightly appearance. As such, using the irradiating step of Hogan in the process of Berta would result in the tablet being unsatisfactory for its

intended purpose. This is a clear indication that a lack of predictability exists in arriving at the claimed invention based on the combination of Berta and Hogan.

The Examiner complains that the Appellants have not shown that the irradiating step of Hogan would be detrimental to the coated tablet of Berta. This argument is without merit. Common sense dictates that irradiating a material to its melting point, as taught in Hogan, would result in the coatings of Berta becoming fluid and flowing on the surface of the tablet. This would be particularly true if heat from irradiation is being introduced into the fluid coating. As noted above, portions of the now fluid coating would run together or flow to one side of the tablet making the tablet have an unsightly and aesthetically unappealing appearance. Accordingly, one of ordinary skill would not have an expectation of success in irradiating the tablets of Berta as taught by Hogan. For this additional reason, Appellants respectfully submit that the rejection of Claims 6 – 9, 11, 13 – 20, and 31 – 47 should be reversed.

In view of the foregoing remarks, it can be seen that the claimed invention is patentable over the cited references because Berta and Hogan, whether considered individually or in combination, fail to disclose or suggest a solid composition having a multicolored continuous film coating layer. Further, one of ordinary skill in the art would not be motivated to modify Berta to include the irradiation step of Hogan as contemplated by the Office. Appellants respectfully requests that the rejection of Claims 6 – 9, 11, 13 – 20, and 31 – 47 be reversed.

D. The combination of Berta and Hogan does not teach a continuous multi-colored coating layer in which the coating layer includes logos, bar codes or letters as part of the coating.

With respect to dependent Claims 18 – 20 and 44 – 47, there is absolutely no teachings in either Berta or Hogan on how their respective teachings can be modified to produce a coating having a pattern, logo, bar code or letters. The Examiner completely fails to disclose how such a coating could be obtained by modifying the cited references. The Examiner glosses over this glaring deficiency by stating that the inclusion of logos, bar codes or letters as instantly claimed does not make the invention patentable since variations in designs or patterns in solid medicament forms is commonly and routinely practice in the pharmaceutical art. This statement

completely fails to address or cite any prior art that teaches a solid preparation having a continuous multi-colored coating layer in which the coating layer includes logos, bar codes or letters as part of the coating. This element is completely missing from the cited art. The fact that it is known to include caplets/tablets with logos, bar codes, or letters does not disclose or suggest a continuous coating layer having such as part of the coating.

Furthermore, the tablet of Berta is dipped into two different baths to produce a multi-colored tablet. There is absolutely no teaching of how such a method could be used to produce a continuous coating with a pattern, such as a logo, bar code or letters in which the pattern is part of the coating. Accordingly, there are absolutely no teachings in either Berta or Hogan of a solid preparation having a continuous multi-colored coating layer in which the coating layer includes logos, bar codes or letters as part of the coating. Accordingly, the rejections of Claims 18 – 20 and 44 – 47 should be reversed for these additional reasons.

E. The Examiner has failed to follow the standard set forth in *Graham v. John Deere*

Finally, the Examiner has failed to follow the standard for making an obviousness rejection as articulated by the Supreme Court in *Graham v. John Deere*, 383 U.S. 1 (1966) and in section 2141 of the MPEP. The crux of the Examiner's reasoning is articulated on page 4 of the Final Office Action. The Examiner states that "Berta explicitly recognizes and teaches a solid medicament comprising a multi-colored, capsule-like coating...." In other words, the Examiner is reasoning that the claimed invention is obvious because two colored tablets are known. This can surely not be the standard by which proper rejections are made.

According to *Graham*, an obviousness analysis includes: (A) determining the scope and contents of the prior art; and (B) ascertaining the differences between the prior art and the claims in issue. See MPEP 2141. The Examiner has failed to do both of these. The Examiner has failed to understand the scope and contents of the prior art. As discussed above, Berta teaches a tablet having two coatings that are separately applied to separate halves of the tablet; Berta does not teach a continuous multi-colored coating. Similarly, Hogan also teaches providing a multi-colored coating by providing separate coatings on each half of the tablet; Hogan does not teach a continuous multi-colored coating. In contrast, the claimed invention recites a tablet having a multicolored continuous coating, which is not taught in Berta or Hogan. Thus, the Examiner has

failed to compare the actual teachings of the references to the claims.

The MPEP further states that in making an obvious rejection “the references must be considered as a whole and must suggest the desirability . . . of making the combination.” See MPEP 2141. The Examiner has also failed to adhere to this tenet of patent law. As discussed above, there are no teachings in the cited references that would motivate one to irradiate the tablet of Berta, and the Examiner has failed to articulate a reasonable motivation for making such a combination. Further, the Examiner’s arguments show that he has based the rejection on what he perceives as the “gist” of the invention, i.e., a two-colored tablet rather than on the structural features recited in the claims. The Examiner’s reasoning completely ignores the claim language and fails to consider the invention as a whole. See MPEP 2141.02.

The Office Action further asserts that the Applicants have failed to demonstrate that the claimed invention has any unexpected or surprising results. However, such a demonstration is unnecessary because the Office has failed to establish a *prima facie* case of obviousness.

From the above discussion, it can be seen that the Examiner has repeatedly failed to follow the standards laid out by the Supreme Court and the MPEP in making an obviousness inquiry. A proper analysis shows that the claimed invention is neither taught nor suggested by the cited references. For these additional reasons, it is respectfully requested that the rejections based on Berta and Hogan be reversed.

8. ***Claims Appendix.***

An appendix containing a copy of the claims involved in the appeal.

9. ***Evidence Appendix.***

No evidence has been submitted to the Examiner or relied upon by the Appellant.

10. ***Related Proceedings Appendix.***

There are not decisions by a court of the Board in related proceedings.

CONCLUSION

In view of the foregoing arguments, Appellant respectfully submits that Claims 6 – 9, 11, 13 – 20, and 31 – 47 are patentable over the cited references. A decision from the Board of Patent Appeals and Interferences reversing the final rejection of the pending claims is therefore earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Timothy J. Balts', with a long horizontal flourish extending to the right.

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CLAIMS APPENDIX

- 1 – 5. Cancelled.
6. (Previously Presented) The solid preparation of claim 31, wherein said solid preparation is a tablet.
7. (Previously Presented) The solid preparation of claim 31, wherein said continuous film coating layer comprises one or more cellulose derivatives as film coating agents.
8. (Previously Presented) The solid preparation of Claim 7, wherein said cellulose derivative is selected from the group consisting of hydroxypropyl methyl cellulose (HPMC), methylcellulose (MC) and hydroxypropyl cellulose (HPC).
9. (Previously Presented) The solid preparation of Claim 8, wherein said cellulose derivative is hydroxypropyl methyl cellulose.
10. Cancelled.
11. (Previously Presented) The solid preparation of claim 31, wherein at least a portion of said film is exposed to radiation under conditions sufficient to fade the exposed colorant.
12. Cancelled.
13. (Previously Presented) The solid preparation of claim 31, wherein at least a portion of said film is exposed to radiation under conditions sufficient to render the exposed colorant semi-transparent.

14. (Previously Presented) The solid preparation of claim 31, wherein said colorant is a food additive.

15. (Previously Presented) The solid preparation of claim 31, wherein said solid preparation further comprises at least one additional layer underlying said continuous film coating layer, said at least one additional layer comprising a colorant to impart a color thereto that is different from the colors of the overlying continuous film coating layer.

16. (Previously Presented) The solid preparation of claim 31, wherein said film coating layer has two or more different colors.

17. (Previously Presented) The solid preparation of claim 31, wherein said film coating layer has a pattern of two or more different colors.

18. (Previously Presented) The solid preparation of claim 17, wherein said pattern comprises a logo.

19. (Previously Presented) The solid preparation of claim 17, wherein said pattern comprises a bar code.

20. (Previously Presented) The solid preparation of claim 17, wherein said pattern comprises letters.

21 – 30. Cancelled.

31. (Previously Presented) A solid preparation coated with a multi-colored continuous film coating layer, prepared by the process of
coating a solid preparation with a continuous film coating layer having one or more colorants; and,

exposing a first part of the coating layer to a first amount of radiation and exposing a second part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration.

32. (Previously Presented) The solid preparation of claim 31, wherein at least a portion of said film coating layer is exposed to radiation under conditions sufficient to render the exposed colorant transparent.

33. (Previously Presented) A solid preparation coated with a multi-colored continuous film coating layer, prepared by the process of

coating a solid preparation with a continuous film coating layer having one or more colorants; and,

changing the coloration of one or more parts of the coating layer by irradiating those parts of the coating layer to the exclusion of the remainder of the coating.

34. (Previously Presented) The solid preparation of claim 33, wherein said solid preparation is a tablet.

35. (Previously Presented) The solid preparation of claim 33, wherein said continuous film coating layer comprises one or more cellulose derivatives as film coating agents.

36. (Previously Presented) The solid preparation of Claim 35, wherein said cellulose derivative is selected from the group consisting of hydroxypropyl methyl cellulose (HPMC), methylcellulose (MC) and hydroxypropyl cellulose (HPC).

37. (Previously Presented) The solid preparation of Claim 36, wherein said cellulose derivative is hydroxypropyl methyl cellulose.

38. (Previously Presented) The solid preparation of claim 33, wherein at least a portion of said film is exposed to radiation under conditions sufficient to fade the exposed colorant.

39. (Previously Presented) The solid preparation of claim 33, wherein at least a portion of said film is exposed to radiation under conditions sufficient to render the exposed colorant transparent.

40. (Previously Presented) The solid preparation of claim 33, wherein at least a portion of said film is exposed to radiation under conditions sufficient to render the exposed colorant semi-transparent.

41. (Previously Presented) The solid preparation of claim 33, wherein said colorant is a food additive.

42. (Previously Presented) The solid preparation of claim 33, wherein said solid preparation further comprises at least one additional layer underlying said continuous film coating layer, said at least one additional layer comprising a colorant to impart a color thereto that is different from the colors of the overlying continuous film coating layer.

43. (Previously Presented) The solid preparation of claim 33, wherein said film coating layer has two or more different colors.

44. (Previously Presented) The solid preparation of claim 33, wherein said film coating layer has a pattern of two or more different colors.

45. (Previously Presented) The solid preparation of claim 44, wherein said pattern comprises a logo.

46. (Previously Presented) The solid preparation of claim 44, wherein said pattern comprises a bar code.

47. (Previously Presented) The solid preparation of claim 44, wherein said pattern comprises letters.